

Appl. No. 09/869,060
Amendment dated: October 3, 2007
Reply to OA of: April 3, 2007

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-57(canceled).

58(new). A method for assaying homocysteine in a sample, said method comprising contacting said sample with a stable aqueous first reagent mixture, said first reagent mixture comprising

- a polyhaptten having at least one hapten moiety per 100kD of its molecular weight and having a molecular weight in the range 500 kD to 3 MD;

- adenosine or an adenosine analog,

- optionally one or more of:

- a reducing agent;

- an agent which promotes precipitation of a complex between the polyhaptten and the primary antibody described below;

- an enzyme capable of converting said adenosine or adenosine analog or a conversion product of S-adenosine homocysteine (SAH) hydrolase;

contacting said sample with a stable aqueous second reagent mixture, said second reagent mixture comprising

- a primary antibody capable of binding to said polyhaptten whereby to produce a complex,

- the homocysteine converting enzyme SAH hydrolase;

- optionally one or more of

- a secondary antibody capable of binding to said complex;

- an agent which promotes precipitation of said complex;

- an enzyme capable of converting said adenosine or adenosine

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analog or a conversion product of said SAH hydrolase;
photometrically detecting said complex; and
relating the photometrically detected complex to the homocysteine content of said sample.

59(new). A method for assaying homocysteine in a sample, said method comprising contacting said sample with a stable aqueous first reagent mixture, said first reagent mixture comprising

a polyhapten having at least one hapten moiety per 100kD of its molecular weight and having a molecular weight in the range 500 kD to 3 MD;
adenosine or an adenosine analog,
optionally one or more of:

a reducing agent;
an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;
an enzyme capable of converting said adenosine or adenosine analog or a conversion product of SAH hydrolase;

contacting said sample with a stable aqueous second reagent mixture, said second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to produce a complex,

optionally one or more of

a secondary antibody capable of binding to said complex;
an agent which promotes precipitation of said complex;
an enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;

contacting said sample with a stable aqueous third reagent mixture, said third reagent mixture comprising

the homocysteine converting enzyme SAH hydrolase;
optionally one or more of
 a secondary antibody capable of binding to said complex;
 an agent which promotes precipitation of said complex;
 an enzyme capable of converting said adenosine or adenosine
 analog or a conversion product of said SAH hydrolase;
photometrically detecting said complex; and
relating the photometrically detected complex to the homocysteine content of said
sample.

60(new). The method as claimed in claim 58 wherein said optional
secondary antibody is present in at least one of said reagent mixtures.

61(new). The method as claimed in claim 58 wherein said complex is
determined nephelometrically or turbidimetrically.

62(new). The method as claimed in claim 58 wherein photometric
determination takes place before complex generation is complete.

63(new). The method as claimed in claim 58 wherein said sample is a serum
or plasma sample.

64(new). The method as claimed in claim 58 wherein at least one of said
reagent mixtures contains said optional agent which promotes precipitation of said
complex.

65(new). The method as claimed in claim 64 wherein said agent which promotes
precipitation is polyethylene glycol.

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66(new). The method as claimed in claim 58 wherein at least one of said reagent mixtures further comprises a carrier protein.

67(new). The method as claimed in claim 58 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

68(new). The method as claimed in claim 67 wherein said backbone structure is porcine thyroglobulin.

69(new). The method as claimed in claim 58 wherein at least one of said reagent mixtures contains said primary and secondary antibodies and additionally contains a chaotropic salt.

70(new). A homocysteine assay reagent kit comprising a stable aqueous first reagent mixture, said first reagent mixture comprising

a polyhapten having at least one hapten moiety per 100kD of its molecular weight and having a molecular weight in the range 500 kD to 3 MD;

adenosine or an adenosine analog,

optionally one or more of:

a reducing agent;

an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;

an enzyme capable of converting said adenosine or adenosine analog or a conversion product of SAH hydrolase;

and a stable aqueous second reagent mixture, said second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to produce a complex;

the homocysteine converting enzyme SAH hydrolase;

optionally one or more of

- a secondary antibody capable of binding to said complex;
- an agent which promotes precipitation of said complex;
- an enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase.

71(new). A homocysteine assay reagent kit comprising A homocysteine assay reagent kit comprising a stable aqueous first reagent mixture, said first reagent mixture comprising

- a polyhapten having at least one hapten moiety per 100kD of its molecular weight and having a molecular weight in the range 500 kD to 3 MD;
- adenosine or an adenosine analog,
- optionally one or more of:

- a reducing agent;
- an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;
- an enzyme capable of converting said adenosine or adenosine analog or a conversion product of SAH hydrolase;

a stable aqueous second reagent mixture, said second reagent mixture comprising a primary antibody capable of binding to said polyhapten whereby to produce a complex,

optionally one or more of

- a secondary antibody capable of binding to said complex;
- an agent which promotes precipitation of said complex;
- an enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;

and a stable aqueous third reagent mixture, said third reagent mixture comprising the homocysteine converting enzyme SAH hydrolase;
optionally one or more of

a secondary antibody capable of binding to said complex;
an agent which promotes precipitation of said complex;
an enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase.

72(new). The kit as claimed in claim 70 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

73(new). The kit as claimed in claim 70, wherein at least one of said reagent mixtures contains said agent which promotes precipitation of said complex.

74(new). The kit as claimed in claim 73 wherein said agent which promotes precipitation is polyethylene glycol.

75(new). The kit as claimed in claim 70 wherein at least one of said reagent mixtures further comprises a carrier protein.

76(new). The kit as claimed in claim 70 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

77(new). The kit as claimed in claim 76, wherein said backbone structure is porcine thyroglobulin.

78(new). The kit as claimed in claim 70 wherein at least one of said reagents contains said primary and said secondary antibodies and additionally contains a chaotropic salt.

79(new). The method as claimed in claim 59 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

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80(new). The method as claimed in claim 59 wherein said complex is determined nephelometrically or turbidimetrically.

81(new). The method as claimed in claim 59 wherein photometric determination takes place before complex generation is complete.

82(new). The method as claimed in claim 59 wherein said sample is a serum or plasma sample.

83(new). The method as claimed in 59 wherein at least one of said reagent mixtures contains said optional agent which promotes precipitation of said complex.

84(new). The method as claimed in claim 59 wherein at least one of said reagent mixtures further comprises a carrier protein.

85(new). The method as claimed in claim 59 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

86(new). The method as claimed in claim 59 wherein at least one of said reagent mixtures contains said primary and secondary antibodies and additionally contains a chaotropic salt.

87(new). The kit as claimed in claim 71 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

88(new). The kit as claimed in claim 71, wherein at least one of said reagent mixtures contains said agent which promotes precipitation of said complex.

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89(new). The kit as claimed in claim 71 wherein at least one of said reagent mixtures further comprises a carrier protein.

90(new). The kit as claimed in claim 71 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

91(new). The kit as claimed in claim 71 wherein at least one of said reagents contains said primary and said secondary antibodies and additionally contains a chaotropic salt.